**IN THE UNITED STATES DISTRICT COURT**
**FOR THE WESTERN DISTRICT OF PENNSYLVANIA**

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| **BENJAMIN P. SALVIO, Individually and as Administrator of the Estate of JANINE M. TRAGESSER, Deceased,** | ) | |
| **Plaintiff,** | ) | |
| | ) | **2:11-cv-00553** |
| **vs.** | ) | |
| **AMGEN INC., a Delaware Corporation; IMMUNEX, INC., a wholly owned subsidiary of AMGEN INC.; WYETH, LLC, a Delaware corporation; and PFIZER, INC., a Delaware corporation,** | ) | |
| **Defendants.** | ) | |

**MEMORANDUM OPINION AND ORDER OF COURT**

Now pending before the court is DEFENDANTS' MOTION TO DISMISS PLAINTIFF'S SECOND AMENDED COMPLAINT FOR FAILURE TO STATE A CLAIM (Document No. 25), with Memorandum of Law in Support of Defendants' Motion to Dismiss Plaintiff's Second Amended Complaint for Failure to State a Claim (Document No. 26); Plaintiff's Opposition to Defendants' Motion to Dismiss Plaintiff's Second Amended Complaint for Failure to State a Claim and MOTION TO AMEND (Document No. 27); and Reply in Support of Defendants' Motion to Dismiss Plaintiff's Second Amended Complaint for Failure to State a Claim (Document No. 29). The motion has been fully briefed and is ripe for disposition.

Factual and Procedural History[1]

The background of this case is fully set forth in the August 18, 2011 Memorandum Opinion and Order of this Court (Document No. 23). In short, the case arises from the death of Janine M. Tragesser ("Decedent"). Plaintiff Benjamin P. Salvio, individually and as the

[1] All facts alleged by Plaintiff in his Second Amended Complaint are taken as true for the purpose of the motion to dismiss.

administrator of Decedent's estate, alleges that Defendants Amgen Inc., Immunex, Inc., Wyeth, LLC, and Pfizer, Inc.[2] (collectively, "Defendants") were "engaged in the design, manufacture, production, testing, study, inspection, mixture, labeling, marketing, advertising, sales, promotion, and/or distribution of pharmaceutical products, including Enbrel." (Second Amend. Compl. at 2-3). Decedent, who suffered from rheumatoid arthritis and had a history of diabetes, took Enbrel continuously between October 2005 and March 2008, when she became ill. (Second Amend. Compl. at 4-5:118-126, 8:245). At that time, Decedent allegedly contracted mucormycosis,[3] a fungal infection of the sinuses, brain, and lungs, which typically attacks those with weakened immune systems. (Second Amend. Compl. at 5: 127-129). Unfortunately, she died from complications related to her infection on May 13, 2010. (Second Amend. Compl. at 9:262-63).

This Court dismissed Plaintiff's Amended Complaint by Memorandum Opinion and Order of August 18, 2011. However, the Court granted Plaintiff leave to amend "to correct technical errors and to clarify legal and factual assertions in support of a negligence claim, including punitive damages, if warranted." *Salvio v. Amgen Inc.*, 2011 WL 3651314, at *11 (W.D. Pa. Aug. 18, 2011). In doing so, the Court cautioned that "[i]f Plaintiff chooses to amend, it will be essential to plead facts that there was a safer product on the market in regard to his design/manufacturing defect claim, and to overcome the learned intermediary doctrine." *Id.*

Since the date of that ruling, Plaintiff has filed a Second Amended Complaint (Document No. 24), which alleges the following claims against all of the Defendants: negligent failure to warn, negligent design/manufacture, and punitive damages. In addition, Plaintiff brings a survival action and a wrongful death action, pursuant to 42 Pa. C.S.A. §§ 8301 and 8302.

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[2] Defendants note that because the period during which Decedent allegedly used Enbrel predates the date upon which Pfizer, Inc. acquired Wyeth, LLC and because Wyeth, LLC continues to exist as separate corporate entity, Pfizer, Inc. is not a proper party to this action. The Court is unable to rule on this issue at the motion to dismiss stage.

[3] Mucormycosis is also known as zygomycosis.

On September 15, 2011, Defendants filed the instant Motion to Dismiss. They argue that Plaintiff has failed to state a claim for either negligent failure to warn or negligent design/manufacture because: (1) Enbrel's Package Insert adequately warned of the risk of consuming the drug; and (2) Plaintiff failed to allege the existence of a feasible alternative, safer design. Additionally, Defendants contend that Plaintiff's punitive damages claim fails because he has failed to adequately plead the degree of intent necessary to sustain an award for punitive damages.

Standard of Review

A motion to dismiss pursuant to Fed. R. Civ. P. 12(b)(6) challenges the legal sufficiency of a complaint. The Court must accept as true all well-pleaded facts and allegations, and must draw all reasonable inferences therefrom in favor of the plaintiff. However, as the Supreme Court made clear in *Bell Atlantic Corp. v. Twombly*, 550 U.S. 554, 555 (2007), the "factual allegations must be enough to raise a right to relief above the speculative level." *Id.* The Supreme Court has subsequently broadened the scope of this requirement, stating that "only a complaint that states a ***plausible*** claim for relief survives a motion to dismiss." *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1950 (2009) (emphasis added).

A district court must conduct a two-part analysis when presented with a motion to dismiss for failure to state a claim. First, the Court must separate the factual and legal elements of the claim. *Fowler v. UPMC Shadyside*, 578 F.3d 203, 210 (3d Cir. 2009). Although the Court "must accept all of the complaint's well-pleaded facts as true, [it] may disregard any legal conclusions." *Id*. at 210-211. Second, the Court "must then determine whether the facts alleged in the complaint are sufficient to show that the plaintiff has a 'plausible claim for relief.' In other words, a complaint must do more than allege the plaintiff's entitlement to relief. A

complaint has to 'show' such an entitlement with its facts." *Id*. at 211 (citing *Iqbal,* 129 S. Ct. at 1949). The determination of "plausibility" will be "'a context-specific task that requires the reviewing court to draw on its judicial experience and common sense.'" *Id*. at 211 (quoting *Iqbal,* 129 S. Ct. at 1950).

Legal Analysis

At the outset, the Court notes that jurisdiction in this case is based on the diverse citizenship of the parties. 28 U.S.C. § 1332(a). Pursuant to 28 U.S.C. § 1332(a), district courts "have original jurisdiction of all civil actions where the matter in controversy exceeds the sum or value of $75,000, exclusive of interest, and is between . . . citizens of different States." *Id.* Complete diversity requires that, in cases with multiple plaintiffs or multiple defendants, no plaintiff be a citizen of the same state as any defendant. *Zambelli Fireworks Mfg. Co. v. Wood*, 592 F.3d 412, 419 (3d Cir. 2010).

Federal courts in diversity actions must apply the substantive laws of the forum state. *Erie R.R. Co. v. Tompkins*, 304 U.S. 64, 78 (1938). Here, all parties presume that Pennsylvania law controls the allegations set forth in Plaintiff's Second Amended Complaint, as will the Court.

Defendants have moved for the dismissal of the Second Amended Complaint in its entirety. The Court will address each of Plaintiff's claims *seriatim*.

A. Documents Considered on Judicial Review

Before addressing Plaintiff's claims, the Court must determine whether to consider the Enbrel Package Insert, which Defendants have attached as an exhibit to their Motion to Dismiss. Plaintiff argues that the Court should not consider the Package Insert in determining the plausibility of Plaintiff's claims. As this Court noted in its Memorandum Opinion of August 18,

2011, "[n]either party disputes the authenticity of the attached document. Furthermore, Plaintiff makes reference to, and thus incorporates by reference, the Enbrel Package Insert in his Complaint, stating 'Defendants purposely ignored and/or understated the risk of such serious infections . . . due to Enbrel's use in its labels, ***package inserts,*** advertisements, marketing and other promotional materials.'" The United States Court of Appeals for the Third Circuit has made clear that "a court may consider any undisputedly authentic document that a defendant attaches as an exhibit to a motion to dismiss if the plaintiff's claims are based on the document." *Pension Benefit Guar. Corp. v. White Consol. Industries*, 998 F.2d 1192, 1196 (3d Cir. 1993) (internal citations omitted). Here, the authenticity of the Enbrel Package Insert is undisputed and both parties have discussed its content at length.

It is well-established that a plaintiff with a legally deficient claim cannot avoid a motion to dismiss simply by failing to attach the dispositive document. *Id.* In this case, Plaintiff has asserted that the warning is inadequate. It is axiomatic that the Court cannot resolve this claim without making reference to the actual warning. Accordingly, the Court's reading of the Second Amended Complaint "is informed by [the Package Insert] . . . of which [it] can take judicial notice." *City of Pittsburgh v. West Penn Power Co.*, 147 F.3d 256, 259 (3d Cir. 1998).

B. Count I -- Negligent Failure to Warn

Plaintiff alleges that Defendants failed to provide adequate warnings regarding the specific risks associated with taking Enbrel to either the Decedent or the physicians who prescribed her the drug. (Second Amend. Compl. at 13:358-59). As this Court noted in dismissing Plaintiff's First Amended Complaint, under Pennsylvania's learned intermediary doctrine, Defendants had no duty to personally warn Decedent of Enbrel's potential side effects. *See Parkinson v. Guidant Corp.*, 315 F. Supp. 2d 741, 748-49 (W.D. Pa. 2004) (internal citations

omitted) (explaining that "a prescription drug manufacturer may meet its duty to warn by providing an adequate warning to a learned intermediary as opposed to the general public"). Accordingly, the Court will consider only the alleged failure to adequately warn Decedent's prescribing doctors.

In support of his failure-to-warn claim, Plaintiff attempts to suggest that the physicians were not warned. Plaintiff does not aver specific facts to show lack of notice, but instead alleges that there is no evidence that Decedent's prescribing doctors actually received the Enbrel Package Insert. Specifically, Plaintiff alleges that "[n]othing in the 9000+ pages of [Decedent's] medical records suggest[s] . . . that the prescribing doctors had been adequately warned." (Second Amend. Compl. at 13:369-72). Plaintiff also contends that the Defendants have not provided any evidence that Decedent's doctors received an Enbrel Package Insert or were made aware of Enbrel's potential risks by any other means, such as advertisements or person-to-person sales calls.

This argument is not persuasive. Contrary to Plaintiff's contention, he – not the Defendants – has the burden of pleading "'sufficient factual matter' to show that the claim is facially plausible." *Twombly*, 550 U.S. at 211 (quoting *Iqbal,* 129 S. Ct. at 1950). Plaintiff has not pleaded any facts tending to make it plausible that the particular packages of Enbrel sent to Decedent's doctors did not have a Package Insert, which Plaintiff concedes typically accompanied Enbrel during the period in which Decedent took the drug. To the contrary, he merely alleges that Plaintiff's medical records make no mention of a warning and therefore baldly concludes that Decedent's doctors must not have received such an insert.[4]

[4] The absence of a mention of the Package Insert in Decedent's medical records is meaningless without an averment regarding whether Decedent's doctors typically placed Package Insert warnings in those records.

Elsewhere in the Second Amended Complaint, Plaintiff effectively concedes the existence of the Package Insert. For example, throughout the Second Amended Complaint, Plaintiff refers to the fact that the Package Insert warned of the risk of bacterial infections like sepsis and tuberculosis to contrast the lack of a similar warning of fungal infections. Likewise, in his brief in opposition, he makes a number of references to "the warnings then in 'effect' (2001 package inserts)." *See, e.g.,* Opposition Brief at 11. Further, he acknowledges "there is no way for plaintiff adequately to plead the facts of this case without mentioning the adequacy of Defendants warnings to [Decedent]." Opposition Brief at 8. Indeed, it appears undisputed that Enbrel was typically accompanied by a twenty-five (25) page Package Insert throughout the entire relevant period, from October 2005 to March 2008.

Substantively, Plaintiff contends that even if Decedent's prescribing doctors had received an Enbrel Package Insert, the warning contained therein was inadequate because it did not specifically warn of the risk of invasive fungal infections such as mucormycosis or the risk of death from such infections. Enbrel's Package Insert, which went into effect in 2001, warns of infections as the primary risk of taking Enbrel. The warning, which appears in large, boldface type near the beginning of the twenty-five (25) Package Insert, appears as follows:

> **WARNINGS: INFECTIONS: IN POST–MARKETING REPORTS, *SERIOUS INFECTIONS AND SEPSIS, INCLUDING FATALITIES*, HAVE BEEN REPORTED WITH THE USE OF ENBREL. MANY OF THE *SERIOUS INFECTIONS* HAVE OCCURRED IN PATIENTS ON CONCOMITANT IMMUNOSUPPRESSIVE THERAPY THAT, IN ADDITION TO THEIR UNDERLYING DISEASE COULD PREDISPOSE THEM *TO INFECTIONS*. RARE CASES OF TUBERCULOSIS (TB) HAVE BEEN OBSERVED IN PATIENTS TREATED WITH TNF ANTAGONISTS, INCLUDING ENBREL. PATIENTS WHO DEVELOP A NEW *INFECTION* WHILE UNDERGOING TREATMENT WITH ENBREL SHOULD BE MONITORED CLOSELY. ADMINISTRATION OF ENBREL SHOULD BE DISCONTINUED IF A PATIENT DEVELOPS A *SERIOUS INFECTION* OR SEPSIS. TREATMENT WITH ENBREL SHOULD NOT BE INITIATED IN PATIENTS WITH ACTIVE**

> ***INFECTIONS*** **INCLUDING CHRONIC OR LOCALIZED INFECTIONS. PHYSICIANS SHOULD EXERCISE CAUTION WHEN CONSIDERING THE USE OF ENBREL IN PATIENTS WITH A HISTORY OF RECURRING *INFECTIONS* OR WITH UNDERLYING CONDITIONS WHICH MAY PREDISPOSE PATIENTS TO *INFECTIONS*, SUCH AS ADVANCED OR POORLY CONTROLLED DIABETES (see PRECAUTIONS and ADVERSE REACTIONS, Infections).**

(Document No. 19-2) (capitalization and bold in original, *emphasis added*) (*See* Document No. 19–2 at 13, 15–16). Similar warnings appear elsewhere in the Package Insert.

Under Pennsylvania's learned intermediary doctrine, the determination of whether a warning provided to a prescribing physician is adequate is initially a question of law. *Mazur v. Merck & Co., Inc.*, 964 F.2d 1348, 1366 (3d Cir. 1992). The adequacy of a prescription drug manufacturer's warning is determined under the "reasonableness" standard set forth in *Restatement (Second) of Torts* § 388. *Incollingo v. Ewing*, 282 A.2d 206, 220 n.8 (Pa. 1971). The manufacturer's duty is based on the information it knew or should have known at the time of the alleged injury. *See Aaron v. Wyeth*, 2010 WL 653984, at *7 (W.D. Pa. Feb. 19, 2010) (internal citations omitted). Accordingly, a prescription drug manufacturer has "a duty to exercise reasonable care to inform those for whose use the article [was] supplied of the facts which make [the product] likely to be dangerous." *Id.* Prescription drug manufacturers' duty to warn runs to the doctor, not the patient or public. *Baldino v. Castagna*, 478 A.2d 807 (Pa. 1984). As explained in *Demmler v. SmithKline Beecham Corp*., 671 A.2d 1151, 1154 (Pa. Super. 1996):

> As a medical expert, the prescribing physician can take into account the propensities of the drug, as well as the susceptibilities of his patient. His is the task of weighing the benefits of any medication against its potential dangers. The choice he makes is an informed one, an individualized medical judgment bottomed on a knowledge of both patient and palliative.

Warnings that "advise[] physicians of the specific risks at issue" are adequate as a matter of law. *Aaron v. Wyeth*, 2010 WL 653984 at 10. For example, in *Aaron*, the plaintiff's adult son

suffered from depression. *Id.* at *1. As a result, he was prescribed an antidepressant medication by his physician. *Id.* at *2. Two weeks after being prescribed the medication, he died of a self-inflicted gunshot wound. *Id.* His father filed suit as the personal representative of his estate, alleging that although the manufacturer of the medication warned of suicidality in children and adolescents, it failed to adequately warn of the risk of suicide in adults. *Id.* at *9.

The Court rejected this argument. The warning at issue "contained more than two (2) pages of suicide related warnings." *Id.* at *8. Along with advising generally of the risks of suicide, it also included "an FDA mandated pediatric 'black box' warning entitled 'Suicidality in Children and Adolescents.'" *Id.* at *8. Apparently as a result of that "black box" warning, the plaintiff's prescribing doctor testified that he believed "the Effexor suicide-related warnings addressed only pediatric and adolescent patients, and not adult patients." *Id.* at *9. The district court found, however, that the prescribing doctor "was aware of the risk for suicide in depressed patients taking antidepressants based upon his training and experience." *Id.* at *10. In light of that, and the fact that the defendant warned broadly of the risk of suicide, the court found the warning adequate and granted summary judgment in favor of the defendant drug manufacturer. *Id.* at *10-11.

The circumstances in this case are analogous. Plaintiff acknowledges that the manufacturer warned physicians broadly about the risk of infection, but contends that Defendants failed to specifically warn of fungal infections. Plaintiff avers that, from a medical perspective, the identification, diagnosis, and treatment of bacterial infections such as sepsis and tuberculosis differs from the identification, diagnosis, and treatment of invasive fungal infections like the one that allegedly caused Decedent's death. (Second Amend. Compl. at 6:148-52). For example, according to the Second Amended Complaint, "[p]atients with invasive fungal

infections might present to a healthcare practitioner with disseminated, rather than localized, disease." (Second Amend. Compl. at 6:152-53). Further, certain testing may return negative results in patients with active fungal infection. (Second Amend. Compl. at 6:153-55). As a result, even a doctor with experience recognizing sepsis or tuberculosis likely has no prior experience identifying invasive fungal infections. (Second Amend. Compl. at 6:156-59). Plaintiff also alleges that Defendants knew or should have known that Enbrel led to an increased risk of invasive fungal infections because, through March 31, 2008, the drug was identified as the primary suspect in seventy-two (72) fungal infection-related deaths, according to the Federal Drug Administration. (Second Amend. Compl. at 10:284-89).

The Package Insert informed Decedent's prescribing doctors of the risk which is alleged to have occurred, i.e. "**SERIOUS INFECTIONS . . . INCLUDING FATALITIES**."[5] As in *Aaron*, where the defendant drug manufacturer warned broadly of the risk of suicide and highlighted that risk with respect to adolescents, the manufacturers of Enbrel issued a broad warning of the risk of infection and highlighted some specific risks, i.e. sepsis and tuberculosis. *Compare Aaron*, 2010 WL 653984, at *8. Furthermore, the warning specifically informed prescribing doctors of the risk of prescribing Enbrel to patients who, like the Decedent, had diabetes, as follows: "**CAUTION WHEN CONSIDERING THE USE OF ENBREL IN PATIENTS WITH A HISTORY OF . . . ADVANCED OR POORLY CONTROLLED DIABETES**." Therefore, the Court finds that the Enbrel Package Insert in effect when Decedent was prescribed the drug adequately warned doctors of the risk of serious infections, such as the

[5] It is illustrative that one medical dictionary definition of infection makes no distinction between *bacterial* and *fungal* infections, such as mucormycosis. *See* Dorland's Illustrated Medical Dictionary, 834 (27th ed. 1988) (defining infection as an "invasion and multiplication of microorganisms in body tissues, which may be clinically inapparent or result in local cellular injury due to competitive metabolism, toxins, intracellular replication, or antigen-antibody response").

one which allegedly led to Decedent's death.

Plaintiff also premises his inadequate warning claim on an alert the FDA issued to healthcare professionals regarding Enbrel on September 4, 2008– some five months after Decedent discontinued her use– on the risk of invasive fungal infections and resulting death. (Second Amend. Compl. at 6:163-66). That alert led Defendants to include a "black box" warning for invasive fungal infections along with the Enbrel Package Insert. Plaintiff contends that this amendment demonstrates the inadequacy of the prior Package Insert which was in effect when Decedent took the drug. (Second. Amend. Compl. at 7:203-39). However, it is well established that such a revision cannot be relied on to establish the inadequacy of Defendants' warning. *See Josephs v. Harris Corp.*, 677 F.2d 985, 991 (3d Cir.1982) (finding that under Fed. R. Evid. 407, the issuance of warning subsequent to the date of plaintiff's injury cannot be used to establish a defendant's negligence); *accord Werner v. Upjohn*, 628 F.2d 848, 854 (4th Cir. 1980) (explaining that plaintiff cannot use "subsequent warning to prove antecedent negligence"); *Stahl v. Novartis Pharma Corp.,* 293 F.3d 254, 270 n. 10 (5th Cir. 2002) (noting that "evidence of subsequent remedial measures cannot be considered in evaluating whether the [earlier] warning was adequate"); *DeLuryea v. Winthrop Laboratories*, 697 F.2d 222, 229 (8th Cir. 1983) (finding that evidence that manufacturer changed wording of package insert warning was inadmissible to establish inadequacy of original warning).

In sum, because the Package Insert warning provided by Defendants advised Decedent's prescribing physicians of the very injury that occurred, the warning was adequate as a matter of law.[6] Accordingly, Defendants' Motion to Dismiss Count I will be **GRANTED**.

[6] The Court does not reach the question of whether Plaintiff adequately pled proximate causation. *See Simon v. Wyeth Pharmaceuticals, Inc*., 989 A.2d 356, 368 (Pa. Super. 2009).

C. Count II -- Negligent Design/Manufacture

Plaintiff alleges that Defendants were negligent in the design and manufacture of Enbrel because feasible safer design alternatives existed, which would have lessened or eliminated the injuries Decedent suffered. In support of his negligent design claim, he identifies three alternative disease-modifying antirheumatic drugs ("DMARDs") that Decedent could have taken. The list includes sulfasalazine (Azulfidine), a sulfa-based DMARD; Hydroxychloroquine (Plaquenil), an anti-malarial drug; and Cyclophosphamide (Cytoxan), a nitrogen-mustard derivative. (Second Amend. Compl. at 16-17). Plaintiff alleges that although each of these drugs have side effects, none of them "suppress[es] the immune system to such a degree that permits invasive fungal infections." (Second Amend. Compl. at 16:429-30). Plaintiff further alleges that each of these drugs were "feasible in that there was no reason that [Decedent] could not have taken [them] and received moderate relief." (Second Amend. Compl. at 16:440-41). Defendants counter that the three drugs identified by Plaintiff as alternative designs are in reality altogether different products. The Court agrees that Plaintiff has failed to plead sufficient facts as to whether any alternative design could have been feasibly employed by Defendants.

The Pennsylvania Superior Court has only recently recognized that a claim for negligent design can be brought against a manufacturer of prescription drugs, notwithstanding the Pennsylvania Supreme Court's adoption of comment K of *Restatement (Second) of Torts* § 402A, which precludes claims for strict liability based on design defects against a prescription drug maker. *Lance v. Wyeth*, 4 A.3d 160, 165-66 (Pa. Super. 2010). The determination of whether a product was negligently designed turns on whether "an alternative, feasible, safer design would have lessened or eliminated the injury plaintiff suffered." *Berrier v. Simplicity Mfg.*, 563 F.3d 38, 64 (3d Cir. 2009) (quoting *Habecker v. Clark Equipment Co.*, 36 F.3d 278,

281 (3d Cir. 1994)).

The Pennsylvania courts have not addressed the issue of whether a seemingly different product can qualify as a feasible alternative design. However, it is instructive that a number of federal district courts, when faced with that issue, have held that "an alternative design must not be an altogether essentially different product." *Michael v. Wyeth, LLC*, 2011 WL 2150112, at *11 (W.D. W.Va. May 25, 2011) (citing *Torkie-Tork v. Wyeth*, *LLC*, 739 F. Supp. 2d 895, 900 (E.D. Va. 2010); *see also Kimball ex rel. Kimball v. RJ Reynolds Tobacco Co.*, 2006 WL 1148506, at *3 (W.D. Wash. April 26, 2006) (finding that a plaintiff "cannot point to an entirely different product as an alternative design"). That analysis is persuasive in this case, as Plaintiff has failed to allege any alternative ways in which Enbrel could have been designed. Instead, he merely lists completely different drugs that Decedent could have taken.

Assuming*, arguendo*, that Plaintiff could establish the existence of safer alternatives, he has nonetheless failed to allege any facts as to whether "a reasonable alternative could have been practically adopted [by Defendants] at the time of sale." *Hoffman v. Paper Converting Machine Co.*, 694 F. Supp. 2d 359, 366 (E.D. Pa. 2010). Rather, Plaintiff alleges that it would have been feasible for *Plaintiff* to take the alternative drugs, an allegation that is immaterial for the purpose of a negligent design/manufacture claim. Accordingly, Defendants' Motion to Dismiss Count II of the Second Amended Complaint will be **GRANTED**.

D. Punitive Damages

In dismissing Plaintiff's First Amended Complaint, this Court concluded that "[i]t is difficult to envision facts that would support a claim for punitive damages in this case." *Salvio*, 2011 WL 3651314, at *10. The Second Amended Complaint again fails to plead such facts. Nonetheless, Plaintiff argues that dismissal would be improper at this stage of the litigation, as

the parties should be allowed to explore the issue through discovery. The Court does not agree.

In Pennsylvania, "a punitive damages claim must be supported by evidence sufficient to establish that (1) a defendant had a subjective appreciation of the risk of harm to which the plaintiff was exposed and that (2) he acted, or failed to act, as the case may be, in conscious disregard of that risk." *Hutchinson ex rel. Hutchinson v. Luddy*, 870 A.2d 766, 772 (Pa. 2005). The defendant's conduct "must be flagrant, grossly deviating from the ordinary standard of care." *Tipton v. Viaquest Behavioral Health of Pa., LLC*, 2010 WL 5258473, at *5 (E.D. Pa. Dec. 23, 2010) (quoting *Albright v. Abington Mem. Hosp.*, 696 A.2d 1159, 1164 (Pa. 1997)). Here, Plaintiff makes the boilerplate allegation that the Defendants' conduct was "aggravated by the kind of malice, fraud and reckless disregard for others, the public, and the Plaintiff for which the law allows the imposition of exemplary or punitive damages." (Second. Amend. Compl. at 17:465-67). He then goes on to list the elements of a claim for punitive damages. (Second Amend. Compl. at 17-18:468-79). He has therefore again failed to allege any conduct that would rise to the level of seriousness necessary for imposing punitive damages and to satisfy the pleading standard of *Twombly*, *Fowler,* and *Phillips*.

Moreover, the Enbrel Package Insert warned of "serious infections," which is the very injury that allegedly caused Decedent's death. Although the Pennsylvania courts have not addressed this issue, several United States Courts of Appeal, faced with circumstances similar to those here, have explained that claims for punitive damages are unfounded where a manufacturer-defendant warns of the potential danger that resulted in injury to a plaintiff. *See, e.g. Dudley v. Bungee Int'l Mfg. Corp.*, 1996 WL 36977, at *3 (4th Cir. Jan. 31, 1996) (finding that "since [defendant] warned of the potential danger that injured [plaintiff], it exhibited some care for his safety" and thus "an award of punitive damages was not warranted under a failure to

warn theory); *Kritser v. Beech Aircraft Corp.*, 479 F.2d 1089, 1097 (5th Cir. 1973) (rejecting claim for punitive damages where defendant takes some steps to warn plaintiff of potential danger because such conduct contraindicates "conscious indifference"); *Toole v. McLintock*, 999 F.3d 1430, 1436 (11th Cir. 1993) (finding that punitive damages were not warranted because defendant's "warning describes the main harms that [Plaintiff] has actually suffered). As a result, even if Plaintiff could show that "[m]ore could have been done or said," the Defendants did not display indifference toward the public's safety and therefore punitive damages are not warranted. *Id.* Defendants' Motion to Dismiss Plaintiff's claim for punitive damages will be **GRANTED**.[7]

E. Wrongful Death and Survival Actions

Plaintiff also asserts claims for wrongful death and survival actions. These are not independent, substantive causes of action, but rather are separate and distinct mechanisms by which a plaintiff may assert underlying claims, such as negligence. *See Sullivan v. Warminster Twp.*, 2010 WL 2164520, * 6 (E.D. Pa. 2010). Therefore, because Plaintiff's underlying claims will be **DISMISSED**, the wrongful death and survival actions will be **DISMISSED** as well.

Leave to Amend

Plaintiff seeks leave to amend his Complaint pursuant to Fed. R. Civ. P. 15(a)(2). Rule 15(a) provides that leave to amend "shall be freely given when justice so requires."As the United States Court of Appeals for the Third Circuit has explained, a district court should grant leave to amend in the absence of undue delay, bad faith, dilatory motive, repeated failure to cure deficiencies, undue prejudice to opposing counsel, or futility of the amendment. *USX v.*

[7] The Court notes that in Pennsylvania, "punitive damages are an element of damages arising out of the initial cause of action, if that cause of action is dismissed, the punitive damages which are incident to actual damages cannot stand." *Kirkbride v. Lisbon Contractors, Inc.*, 555 A.2d 800, 101 (Pa. 1989). Accordingly, with respect to Plaintiff's negligent design/manufacture claim, because the underlying claim will be dismissed, the claim for punitive damages could not stand on its own.

*Barnhart*, 395 F.3d 161, 166 (3d Cir. 2004).

However, Plaintiff has already filed three complaints in this case. In the Memorandum Opinion and Order of August 18, 2011, the Court cautioned Plaintiff that in order to survive another motion to dismiss, he would have to plead facts to show that a safer design was available and overcome the learned intermediary doctrine. Plaintiff has again failed to plead valid claims for negligent failure to warn or negligent design/manufacture. With respect to the punitive damages claim, rather than curing the deficiencies which were previously pointed out by the Court, Plaintiff again merely pleaded conclusory allegations. As a result, Plaintiff's Motion for Leave to Amend will be **DENIED** as futile and prejudicial to Defendants.

Conclusion

In conclusion, Defendants' Motion to Dismiss will be **GRANTED;** Plaintiff's Motion to Amend will be **DENIED;** and the case will be docketed closed.

An appropriate Order follows.

McVerry, J.

**IN THE UNITED STATES DISTRICT COURT**
**FOR THE WESTERN DISTRICT OF PENNSYLVANIA**

| | | |
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| **BENJAMIN P. SALVIO, Individually and as Administrator of the Estate of JANINE M. TRAGESSER, Deceased,** | ) | |
| **Plaintiff,** | ) | |
| | ) | **2:11-cv-00553** |
| **vs.** | ) | |
| **AMGEN INC., a Delaware Corporation; IMMUNEX, INC., a wholly owned subsidiary of AMGEN INC.; WYETH, LLC, a Delaware corporation; and PFIZER, INC., a Delaware corporation,** | ) | |
| **Defendants.** | ) | |

**ORDER OF COURT**

AND NOW, this 15th day of February, 2012, for the reasons set forth in the foregoing Memorandum Opinion, it is hereby **ORDERED, ADJUDGED and DECREED** that DEFENDANTS' MOTION TO DISMISS PLAINTIFF'S SECOND AMENDED COMPLAINT FOR FAILURE TO STATE A CLAIM (Document No. 25) is **GRANTED;** and Plaintiff's MOTION TO AMEND is **DENIED**. The clerk shall docket this case closed.

BY THE COURT:

/s/ Terrence F. McVerry
United States District Court Judge

cc: **George L. Garrow, Jr., Esquire**
Email: ggarrow@garrowandevans.com

**Paul Lagnese, Esquire**
Email: paull@bergerlagnese.com

**John E. Hall, Esquire**
Email: jhall@eckertseamans.com